

Remarks

Entry of the foregoing and reconsideration of the application identified in caption as amended, pursuant to and consistent with the Rules of Practice in Patent Cases, and in light of the remarks which follow, is respectfully requested.

By the present amendment, claim 1 has been amended and claim 29 has been deleted, so that claims 1, 2, 4-15, 17-27, and 33-43 will be pending. Presently, claims 1, 2, 4, 11, 12, 14, 15, 17-20, 27, and 33-43 are under examination and claims 5-10, 13, and 21-26 have been withdrawn from consideration as being directed to non-elected invention(s). Support for the amendment to claim 1 can be found in the specification at least at page 21, lines 23 to 25. Accordingly, no new matter has been presented by the proposed amendments.

The disclosure is objected to because of a lack of the titled section "Brief Description of Drawings" followed by brief description of the several views of the drawings. This rejection has been traversed by amending the specification to include the necessary text. Support for the amendments to the specification can be found at least at page 20, lines 1-15; page 35, line 20 through page 37, line 8; and in the drawings. Accordingly, no new matter has been presented by the proposed amendments.

Claims 1, 2, 4, 11, 12, 14, 15, 17-20, 27, 29, and 33-43 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,004,538 to Hughes et al. ("Hughes") in view of U.S. Patent No. 4,568,540 to Asano et al. ("Asano"). This rejection is respectfully traversed.

The Examiner considers that Hughes discloses the claimed composition, and while teaching that the composition can be acidic, does not specifically teach a pH of from 1.5 to 3.5 or from 2 to 3. Asano is cited for teaching that the dentifrice composition should be maintained at an acidic pH of 3.5 to 6 in order to permit the fluoride to remain in solution instead of precipitating. The Examiner considers a pH range of from 3.5 to 6 to overlap a pH range of from 1.5 to 3.5 so that it would have been obvious to modify the pH of the Hughes composition with the expectation of maintaining the fluoride and zinc ions in solution, as taught by Asano. Based upon the proposed combination of references, the Examiner further considers the artisan to have the skills to adjust the pH to within a range of from 2 to 3 since the fluoride ions would still remain in solution at that pH.

Applicants submit that the present invention is not rendered obvious by the cited prior art. Moreover, even if a skilled person had combined the teachings of Hughes and Asano as suggested by the Examiner he would not have arrived at the claimed compositions.

The present invention pertains to liquid compositions for desensitizing teeth which comprise a non-polymeric acid having protein and calcium-precipitating properties, an organic polymer which has carboxyl and/or hydroxyl groups, a film forming component, and a solvent. According to claim 1, as amended above, the pH value of the composition is in the range of from 2 to 3.

In the present office action the Examiner lists all components disclosed by Hughes and argues that it would have been obvious to a skilled person to combine all these components into one single composition. The Examiner completely ignores the fact that Hughes clearly distinguishes between different types of compositions such as toothpastes, denture cleansing liquids and pastes (column 5, lines 28-29). As set forth therein, each listed component is not compatible with each type of composition. For example, denture cleanser compositions may additionally comprise effervescence generators (column 7, lines 47-50). Effervescence generators contain an alkali metal carbonate or bicarbonate in admixture with an organic acid (column 8, lines 13-23). Upon contact with water the alkali metal carbonate or bicarbonate reacts with the acid and carbon dioxide is released. As has been explained by applicant, effervescence generators can only be used in solid compositions because the carbonate and the acid immediately react upon contact with water. According to Hughes acids are only disclosed as a component of the effervescence generators. Effervescent generators are typically used as disintegration agents for tablets.

The Examiner disagrees with applicant's position that acid is only present in the solid compositions, and argues that Hughes also contemplated liquid denture cleansing compositions, that the effervescence generators were effective under acid, neutral or alkaline conditions, and that therefore applicant's contention that acid must necessarily react with the effervescence generator is not supported by the disclosure of Hughes.

Applicant disagrees. Attached is a copy of several pages of "Remington: The Science and Practice of Pharmacy." This text book confirms that effervescence generators are only stable under dry conditions and that the acid reacts with bicarbonate or carbonate upon contact with water:

"Effervescent granules contain sodium bicarbonate and either citric acid, tartaric acid, or sodium biphosphate in addition to the active ingredients. On solution in water, carbon dioxide is released as a result of the acid-base reaction."

(page 718, right column, "Oral Powders", second paragraph)

“Effervescent Tablets - In addition to the drug substance, these contain sodium bicarbonate and an organic acid such as tartaric or citric. In the presence of water, these additives react liberating carbon dioxide that acts as a disintegrator and produces effervescence.”

(page 890, paragraph bridging left and right column)

And finally:

“An effervescent tablet requires a barrier to moisture, for example, whereas an oil-based product must be protected from oxygen-induced oxidation.”

(page 1048, right column, first paragraph; emphasis added).

The Remington text book thus confirms that the components of effervescence generators, i.e. acid and bicarbonate or carbonate react upon contact with water and must therefore be protected from moisture, and that effervescence generators are only used in solid compositions such as oral powders or tablets.

The Examiner further contends that the ordinary skilled artisan would have been motivated to maintain the pH of the composition of Hughes at acid pH of from 3.5 to 6 as suggested by Asano with the expectation of maintaining the fluoride and zinc ions in solution.

Claim 1 as presently amended requires a pH of 2 to 3. Asano does not suggest to use a pH value below 3.5 and it was therefore not obvious from this document to adjust the pH of the compositions disclosed by Hughes to the claimed range. To the contrary, in the examples of Hughes, pH values of 4.0 to 5.5 are used (column 8, Table II).

It is usually desirable to produce dental cleansing compositions having a neutral pH as is evident for instance from the entry “Toothpaste” in Wikipedia, copy enclosed:

“Ingredients such as baking soda, enzymes, vitamins, herbs, calcium, calcium sodium phosphosilicate, mouthwash, and/or hydrogen peroxide are often combined into base mixes and marketed as being beneficial. Some manufactures add antibacterial agents, for example triclosan or zinc chloride, to prevent gingivitis. Triclosan is a common ingredient in the UK. Bases such as sodium hydroxide are also used to neutralize acids.”

(see Wikipedia, page 3, last paragraph; emphasis added)

It follows that a skilled person would have used as little acid as possible in order to prevent the precipitation of fluoride ions, i.e., a skilled person would have attempted

to adjust the pH to the upper limit of the range of 3.5 to 6 of Asano. Under no circumstances a skilled person reading Asano would have used a pH of 3 or less, as suggested by the present inventors.

The Examiner regards the declaration of Carlo Bolis to be insufficient to overcome the rejections of the claims because the composition used in the determination of the pH is said not to be commensurate in scope with the claims.

Carlo Bolis determined the pH of the composition of Example 5 of the present application. This composition was used for the tests described in Example 8 of the application. The composition of Example 5 is a composition according to claim 1. It comprises a non-polymeric acid having protein and calcium-precipitating properties (phosphonic acid), organic polymers which have carboxyl and/or hydroxyl groups (polyacrylic acid; polyethylene glycol; hydroxypropyl cellulose), and a solvent (ethanol/water). The pH of this solution was determined by Mr. Bolis to be 2.73 which is within the pH range 2 to 3. Having regard to the fact that the claimed range is rather narrow, it is believed that a single measurement at a pH of 2.7 is sufficient to support the full pH range of 2 to 3.

The Examiner objected to the fact that Mr. Bolis has not compared the claimed composition with the composition of the prior art. In this regard it should be noted that the prior art does not describe a composition which would allow a reasonable comparison. Hughes and Asano are concerned with compositions for cleaning teeth and dentures (Hughes) or dental hygiene compositions (Asano) and do not describe compositions for desensitizing teeth. Asano explicitly teaches compositions which do not result in the formation of a precipitate or haze (column 8, lines 23-26), and it is evident that these compositions can therefore not cause the formation of plugs within the dentinal tubules which is an important feature of the claimed compositions.

The examples of Hughes are either solid compositions comprising an excess of base (carbonate and bicarbonate; Examples I to V), or toothpaste/denture cleansing pastes comprising calcium carbonate as abrasive and water (Examples VI to VII) which are incompatible with acids. As is evident from the Remington text book, a skilled person would not have added an acid to a liquid composition comprising calcium carbonate because the acid would have immediately reacted with the carbonate with formation of carbon dioxide. Thus, the abrasive would have been depleted or removed totally from the composition by the reaction with acid. Even if a skilled person had added phosphonic acid as chelating agent to

the liquid compositions of any one of Examples VI to VII, as suggested by the Examiner, the pH of the compositions would have remained within the alkaline range because any acid would have been neutralized by the carbonate or bicarbonate. For achieving an acid pH all of the carbonate must be neutralized. The complete neutralization of the carbonate, i.e., the removal of the abrasive, does not make sense from a technical point of view. Compositions comprising a pH in the range disclosed by Asano do not cause the formation of plugs.

The present invention pertains to liquid compositions for the desensitization of teeth including an acid, an organic polymer, a film-forming agent, and a solvent, having the recited properties and pH. It has been found by the present inventors that these compositions deeply penetrate into dentinal tubules. By reaction with dentinal fluid proteins they form massive plugs and thus reduce the sensitivity of the teeth (page 20, lines 1 to 8 and 17 to 23 of the present application). To achieve the desired formation of a plug, it is necessary to use acids having protein and calcium precipitating properties. The resulting formation of such plugs is surprising since acids usually have a sensitizing effect rather than a desensitizing effect (page 20, lines 7 to 8 of the present application).

The inventors have demonstrated that the compositions of the present invention result in the formation of massive plugs which deeply penetrate into dentinal tubules (page 36, Example 8, in particular lines 31 to 35 in combination with Figures 3 and 5; page 36, line 38 to page 37, line 8; and Figure 6 of the present application) even if the natural pressure of dentinal fluid is simulated.

Accordingly, for at least the reasons noted above, the proposed combination of Hughes and Asano would not render obvious the presently claimed invention. Withdrawal of the record rejection and allowance of all claims is respectfully requested.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is hereby earnestly solicited.

Respectfully submitted,

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